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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,620	03/24/2004	Jessie L.-S. Au	TNI-2-011	4039

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
08/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/807,620	AU ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *06 July 2009*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: *22,26-28,30 and 32-34*.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/James D Anderson/
Examiner, Art Unit 1614

Continuation of 3. NOTE: Applicant's proposed amendments after Final rejection would raise new issues and would require further consideration. Applicant's proposed amendments to claim 22 drastically change the scope of the invention by now requiring the previously optional determination of suramin doses in steps (b1)-(b3). Further, claim 22 does not end in a period in the proposed amendment. Lastly, the proposed amendment to claims 26 is confusing because the claim recites "one the cytotoxic agents is one or more of...". It is not clear how ONE cytotoxic agent can be one OR MORE of the recited agents .

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have been carefully considered but they are not deemed to be persuasive. The rejections of claims 22, 26-28, 30, and 32-34 are maintained for the reasons of record. To the extent that Applicant's arguments require that the proposed claim amendment be entered, such arguments are not persuasive because the proposed amendments will not be entered for the reasons discussed supra.

Applicants argue that Agyin provides limited data to support enablement for the treatment of cancers. This argument is not persuasive because the claims are not drawn to a method of treatment and the rejection of record is not made on the basis of treating cancer. Rather, Agyin motivates one skilled in the art to combine a benzimidazole anticancer agent disclosed therein with a potentiator such as suramin and additional anticancer agents in a kit as recited in the instant claims.

Secondly, Applicants argue that Agyin does not teach a suramin combination. The fact that there are a multitide of possible combinations suggested by Agyin is not pertinent to the present rejection because it would be routine for the skilled artisan to combine a benzimidazole compound disclosed in Agyin with ANY chemotherapeutic agent. Further, the claims are not limited to any particular cytotoxic agents and are thus also drawn to a an unlimited number of possible combinations of suramin with other cytotoxic agents.

Thirdly, Applicants argue that Agyin does not teach using suramin as a potentiator. This is not persuasive because the claims are not limited to kits containing a particular amount of suramin or cytotoxic agent. The fact that suramin leads to sensitization only at lower doses is not pertinent to the patentability of the claimed KITS. Applicants predicate patentability of their claimed kits on the nomogram that is required to enable the use of the kit containing suramin. Applicants allege that the inventive element of the instructions that enable application of medicaments and that provide a functional relationship between printed matter and the claimed kit. This is not persuasive because the instructions do not control what is IN the kit. Put another way, the recited instructions have no bearing and place no limitations on the components of the kit or the content of the kit. Rather, the instructions only tell one skilled in the art how to administer the components of the kit. As such, there is not a functional relationship between the instructions and the claimed kit.

If the Office were to accept Applicant's arguments, inventors could theoretically patent a multitude of kits containing suramin and a cytotoxic agent that differ ONLY in the content of the instructions. For example, it would be possible, using Applicant's rationale, to patent two kits containing suramin and paclitaxel, wherein one kit contains the claimed nomogram for determining the amount of suramin to administer and another kit contains a different set of administration instructions. A third kit containing an even different set of administration instructions could also be theoretically patented. The number of possible kits, containing the SAME active agents could theoretically be patented based ONLY on a difference in the instructions for administration of the active agents. This is clearly what the court in Ngai was seeking to avoid when they said, "If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product. This was not envisioned by Gulack".

For at least these reasons and the reasons set forth in the previous Office Action, the rejections of claims 22, 26-28, 30, and 32-34 are maintained.